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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,670	09/08/2003	Yoshio Onuki	15228A	2150

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EXAMINER

LEUBECKER, JOHN P

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 08/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Taka

Office Action Summary	Application No. 10/657,670	Applicant(s) ONUKE ET AL.	
	Examiner John P. Leubecker	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 10/059,681.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/8/03 & 5/13/04</u> | 6) <input type="checkbox"/> Other: _____ |

Claim Objections

1. Claims 1 and 3 are objected to because of the following informalities: As to claims 1 and 3, lines 3-4, phrase "medical guide wire comprising:" should be --medical guide wire further comprising:-- since it is previously recited that the medical guide wire comprises a guide wire body.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-4, 6, 9 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Soukup (US 2004/0267162).

Soukup discloses a guide wire body (12, Fig.3) and a fixing portion (14) formed of substantially wire-shaped retainer having one end coupled to the distal end portion side (20) of the guide wire body ([0017]) and the other end extending to the proximal end portion side (16). It is noted that the phrase "used to fix the position of said medical guide wire by means of said retainer lest the position of said medical guide wire relative to said endoscope change" is

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regarded as intended use since it does not import any structural limitations for the fixing portion into the claim. As to claim 2, the retainer is formed of a metal ([0026]). As to claim 3, in addition to what is described above, note that the retainer (retaining wire) is parallel to the guide wire body (Fig.3). As to claim 4, note that the junction of the retainer and guide wire body is "welded, crimped or otherwise secured" ([0017]). Both welded, and especially crimped, securements are, in most cases, "separable", as well as many connections conceivably contemplated by "otherwise secured" (e.g., glue, solder, set screw, etc.). As to claim 6, since the guide wire body extends through the retainer, they can be considered side by side, and their respective sectional shapes (cylindrical) are "circular" when joined together. As to claim 9, the retainer is a flat ribbon-shaped ([0026]). As to claim 10, considering handle (16) as being the proximal end portion of the retaining wire, the larger diameter of the handle (16) meets the limitation of claim 10.

4. Claims 1-6, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Magram (U.S. Pat. 5,902,254).

Referring mainly to Figures 13 and 14, Magram discloses a guide wire body (151) and a fixing portion (162) formed of substantially wire-shaped retainer having one end coupled to the distal end portion side (163) of the guide wire body and the other end extending to the proximal end portion side (Fig.13). It is noted that the phrase "used to fix the position of said medical guide wire by means of said retainer lest the position of said medical guide wire relative to said endoscope change" is regarded as intended use since it does not import any structural limitations for the fixing portion into the claim. As to claim 2, note col.11, lines 14-15. As to claim 3, in

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addition to what is described above, note that the retainer (retaining wire) is parallel to the guide wire body (Figs.13 and 14). As to claim 4, one can read the embodiment of Figure 7 to meet the limitations of claim 3 (guide wire body 74, retaining wire 70), wherein col.4, lines 23-31 teaches a separable junction. As to claim 5, the distal most bead forms a coupling member which can be a plastic (col.11, lines 9-11). As to claim 6, with either of the embodiments shown in Figures 13 or 7, the cross sectional shape of the combined, side by side elements will be circular (note Fig.8). As to claims 13 and 14, note col.3, lines 35-36.

5. Claims 1-3, 6 and 7 are rejected under 35 U.S.C. 102(a and e) as being anticipated by Biagtan et al. (U.S. Pat. 6,146,339).

Biagtan et al. discloses a guide wire body (18, Fig.1) and a fixing portion (12) formed of substantially wire-shaped retainer having one end coupled to the distal end portion side (19) of the guide wire body and the other end extending to the proximal end portion side (17). It is noted that the phrase "used to fix the position of said medical guide wire by means of said retainer lest the position of said medical guide wire relative to said endoscope change" is regarded as intended use since it does not import any structural limitations for the fixing portion into the claim. As to claim 2, note that retainer (12) can be a polymer (col.5, line 27). As to claim 3, in addition to what is described above, note that the retainer (retaining wire) is parallel to the guide wire body (Fig.1). As to claims 6 and 7, noted combined cross-sectional shape (Fig. 6A) wherein retainer (12) is arcuate having a crescent shape.

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6. Claims 1, 3, 4, 8, 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Nagamatsu (U.S. Pat. 5,762,070).

Referring mainly to Figures 10 and 11, Nagamatsu discloses a guide wire body (65) and a fixing portion (61) formed of substantially wire-shaped retainer having one end coupled to the distal end portion side of the guide wire body (as can be seen in Figure 10, tube 51 "couples" the guide wire body 65 and retainer 61) and the other end extending to the proximal end portion side (portion near base 64). It is noted that the phrase "used to fix the position of said medical guide wire by means of said retainer lest the position of said medical guide wire relative to said endoscope change" is regarded as intended use since it does not import any structural limitations for the fixing portion into the claim. As to claim 3, in addition to what is described above, note that the retainer (retaining wire) is parallel to the guide wire body (Fig. 10). As to claim 4, the guide wire body (65) and retainer (61) are clearly "separable". As to claim 8, the material of tube (51) that form lumens (52) and (53) provide individual insulating coating layers for the guide wire body (65) and the retainer (61). As to claim 15, note that the combination of guide wire body and retainer are meant to be inserted into an endoscope channel (note Figure 4 and col.7, lines 61-67). The base (64) inherently holds the retaining wire (61) at the proximal end of the endoscope (the proximal end of the instrument channel).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soukup in view of Magram.

Soukup, as described above, fails to disclose any particular length of the guide wire (e.g., retainer). Magram discloses that the length for a guide wire between 50-300 cm is a sufficient length for a guide wire (col.3, lines 32-38). It would have been obvious to one of ordinary skill in the art at the time of the invention to have made the between 50-300 cm, not only because such choice in length would be left up to the whims of the skilled artisan, but also because Magram teaches that this would be a sufficient length for a guide wire.

9. Claims 1, 3, 4, 10-12, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagamatsu in view of Windheuser et al. (U.S. Pat. 6,096,009).

Referring mainly to Figures 3 and 4, Nagamatsu disclose a guide wire body (1a), a fixing portion (retaining wire) (19) and endoscope (20) with channel (21), as claimed. What Nagamatsu fails to disclose in the embodiment of Figures 3 and 4 is a wire fixing portion on the endoscope for holding the proximal end portion of the retaining wire (note proximal end portion 22 in Figure 4). However, Windheuser et al. teaches a wire fixing portion (note Figures 10-12) mounted onto an endoscope for selectively securing the position of the guide wire relative to the endoscope (col.2, lines 47-51). Windheuser et al. teaches that use of such wire fixing device overcomes many disadvantages of the prior art (col.3, lines 47-48), frees the hands of the physician during the procedure (col.2, lines 40-44), and will reduce the chance of inadvertent movement of the guide wire during the procedure (col.1, lines 20-25). For all of these reasons, it

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would have been obvious to one of ordinary skill in the art to have provided a wire fixing device of Windheuser et al. with the endoscope and guide wire of Nagamatsu (Fig.4).

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Due to the fact that the claims are overly broad, only a few of the many relevant references that anticipate or make obvious the claims.

Damadian (U.S. Pat. 6,165,139)

Komiya (U.S. Pat. 4,245,624)

Brennen et al. (U.S. Pat. 5,662,119)

Quinn (U.S. Pat. 5,498,249)

Ischinger et al. (U.S. Pat. 5,131,407)

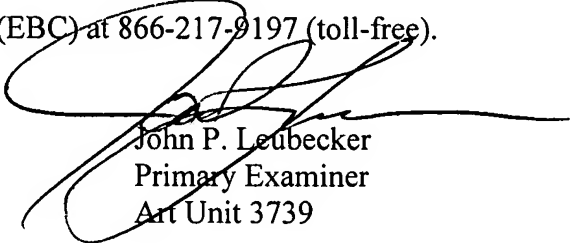
Osypka (U.S. Pat. 5,003,990)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P. Leubecker whose telephone number is (571) 272-4769. The examiner can normally be reached on Monday through Friday, 6:00 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



John P. Leubecker
Primary Examiner
Art Unit 3739

jpl